K120625

510(k) Summary

JUL 25 2012

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Name, Address, Contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
Phone: (317) 521-2458
Fax: (317) 521-2324
Email: colleen.adams@roche.com

Contact Person: K. Colleen Adams, Regulatory Affairs Principal

Date Prepared: February 29, 2012

Device Name

Proprietary name:	(1) Elecsys HSV-1 IgG Immunoassay (2) PreciControl HSV
Common name:	(1) HSV-1 IgG (2) PreciControl HSV
Classification name:	(1) Class 2, 21 CFR 866.3305, Herpes simplex virus serological assays (2) Class 1, 21 CFR 862.1660, Quality control material (assayed and unassayed)
Product Code:	(1) MXJ (2) JJX
Predicate Device:	Focus HerpeSelect 1 and 2 Immunoblot IgG (K000238)

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Device Description

(1) The Elecsys HSV-1 IgG immunoassay is a two-step sandwich immunoassay with streptavidin microparticles, biotinylated recombinant HSV-1-specific antigen labeled with a ruthenium complex and electrochemiluminescence detection. This assay is a qualitative test based on a cut-off formula dependent on the negative and positive calibrators. Cut-off index (COI) is based on the ratio of assay signal to cut-off signal (also abbreviated s/co). COI values greater than or equal to 1.0 are considered positive for the presence of anti-HSV-1 IgG antibody. Results are determined using a two-point calibration. The test system contains the human serum-based calibrators intended for use with the system.

(2) PreciControl HSV contains lyophilized control serum based on human serum. The controls are used for monitoring the accuracy of the Elecsys HSV-1 IgG immunoassay.

Note: The reagents and calibrator are packaged together in the Elecsys HSV-1 IgG immunoassay, while the associated PreciControl is packaged separately.

Intended Use/Indications for Use

Elecsys HSV-1 IgG Immunoassay:
The Roche Elecsys HSV-1 IgG immunoassay is a test for the *in vitro* qualitative determination of IgG class antibodies to HSV-1 in human serum and lithium-heparin plasma, K_2–EDTA plasma, and K_3–EDTA plasma. The test is intended for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-1 infection. The predictive value of positive and negative results depends on the population's prevalence and the pretest likelihood of HSV-1. The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

The test is not FDA cleared for screening blood or plasma donors.

The performance of this assay has not been established for use in a pediatric population, neonates, immunocompromised patients, or for use at point of care facilities.

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Intended Use/Indications for Use, continued	PreciControl HSV: PreciControl HSV is used for quality control of the Elecsys HSV-1 IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Substantial Equivalence	The Elecsys HSV-1 IgG test system is substantially equivalent to other devices legally marketed in the United States. (1) Elecsys HSV-1 IgG immunoassay is equivalent to HerpeSelect 1 and 2 Immunoblot, MRL/Focus Diagnostics (K000238). (2) PreciControl HSV is equivalent to the Elecsys PreciControl Anti-CCP (K081338).
Substantial Equivalence - Comparison	The following tables compare the Elecsys HSV-1 IgG immunoassay and PreciControl HSV with their respective predicate devices.

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Comparison of Assays—Similarities and Differences

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
General Assay Features		
Intended Use/ Indications for Use	The Roche Elecsys HSV-1 IgG immunoassay is a test for the *in vitro* qualitative determination of IgG class antibodies to HSV-1 in human serum and lithium-heparin plasma, K_2–EDTA plasma, and K_3–EDTA plasma. The test is intended for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-1 infection. The predictive value of positive and negative results depends on the population's prevalence and the pretest likelihood of HSV-1. The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for use in a pediatric population, neonates, immunocompromised patients, or for use at point of care facilities.	Focus Diagnostics' HerpeSelect 1 and 2 Immunoblot IgG test is intended for qualitatively detecting the presence or absence of human IgG class antibodies to HSV-1 and HSV-2 in human sera. The test is indicated for testing sexually active adults or expectant mothers for aiding in the presumptive diagnosis of HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2 infection. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, for use by a point of care facility or for use with automated equipment.
Assay Protocol	Sandwich assay	Nitrocellulose immunoblot
Detection Protocol	Electrochemiluminescent Immunoassay	Alkaline phosphatase (qualitative)
Applications	18 minutes	Manual procedure

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
General Assay Features		
Instrument Platform	Elecsys 2010, MODULAR ANALYTICS E170, **cobas e** 411, **cobas e** 601, and **cobas e** 602	Manual procedure
Sample Volume	20 µL	20 µL
Sample Type	Human serum and Lithium-heparin, K_2-EDTA, and K_3-EDTA plasma	Human serum
Reagents	Reagents consist of streptavidin-coated microparticles, biotinylated HSV-1 antigen (recombinant, from *E. coli*), ruthenylated HSV-1 antigen, and negative and positive calibrators.	Reagents consist of HSV-1 and HSV-2 differentiation antigen strips, alkaline phosphatase-conjugated goat anti-human IgG, bromo-chloro-indodyl phosphate and nitroblue tetrazolium substrate and negative and positive controls.
Calibrator	Included with the reagent kit	Not included with this qualitative test
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer). Renewed calibration is recommended as follows: • After 1 month (28 days) when using the same reagent lot. • After 7 days (when using reagents kept on board the analyzer). • As required: e.g. quality control findings outside the specified limits	Calibrators are not included for this qualitative assay. Negative and positive controls are run with every test.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
General Assay Features		
Controls	PreciControl HSV	Negative and positive controls are included with the Focus kit.
Traceability / Standardization	The Elecsys HSV-1 IgG immunoassay has been standardized against a Roche standard. The units have been selected arbitrarily.	There is no standardization for this qualitative assay.
Reagent Stability	**Reagents, ready to use:** Unopened at 2-8°C - up to the stated expiration date After opening at 2-8°C – 8 weeks On the analyzers – 21 days **Calibrators (lyophilized):** Unopened at 2-8°C – up to stated expiration date After reconstitution at 2-8°C – 14 days On the Elecsys 2010 and **cobas e** 411 20-25°C – up to 5 hours On the MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 602 – use only once	Kits and reagents are stable through the end of the month indicated on their expiration dates when stored at 2-8°C.
Cutoffs	The analyzer automatically calculates the cutoff based on the measurement of Cal 1 and Cal 2. The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index.	Positive or negative results are generated by this qualitative assay by comparing bands on the nitrocellulose to a cut-off/control strip.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
General assay features		
Cutoffs (continued)	For the Elecsys HSV-1 IgG immunoassay, the interpretation of the results is: Non-reactive < 1.0 COI Reactive ≥ 1.0 COI	
Result Interpretation	Samples with a cutoff index < 1.0 are non-reactive in the Elecsys HSV-1 IgG immunoassay. These samples are considered negative for HSV-1 IgG-specific antibodies and do not need further testing. Samples with a cutoff index of ≥ 1.0 are considered reactive in the Elecsys HSV-1 IgG immunoassay.	Compare each band on a strip relative to the reading control band. The reading control band is the IgG-2 band on the Cutoff/Positive Control strip. If the band is as dark, or darker than the reading control band, then the band is reactive (+). Likewise, if the band is lighter than the reading control band, then the band is unreactive (neg.). The overall band reactivity is then used to interpret results.
Limits of Measurement	LoB = 0.030 COI LoD = 0.044 COI	Not applicable to this qualitative test
Hook Effect	No hook effect up to 10 COI	Not tested

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
Labeled Performance Characteristics		
Precision	*Intra-assay:* Low Control: SD 0.003 COI High Control: CV 1.0% Serum Samples < 0.8 COI: SD 0.001 – 0.006 COI Serum Samples > 0.8 COI: CV 1.0 – 1.3% *Inter-assay:* Low Control: SD 0.006 COI High Control: CV 2.5% Serum Samples < 0.8 COI: SD 0.001 – 0.012 COI Serum Samples > 0.8 COI: CV 2.6 – 2.9%	Inter Laboratory Reproducibility: An internal investigator and 2 external laboratories assessed the device's reproducibility. Seven samples were run in triplicate on 3 different days. Using the Focus Elisa Index (negative if less than 0.90, equivocal if between 0.90 and 1.10, and positive if greater than 1.10) the manufacturer was able to demonstrate 100% agreement with intra-assay, inter-assay, inter-lot and inter-lab precision testing.
Analytical Specificity	129 HSV-negative specimens, which were positive for the following cross reactants, were tested with the Elecsys HSV-1 IgG immunoassay and the comparator assay: Antinuclear antibodies, Varicella zoster virus, Human indefficiency virus, Cytomegalovirus, *Neisseria gonorrhea, Toxoplasma gondi, Chlamydia trachomatis, Candida albicans,* Epstein Barr virus, Rubella, *E. Coli, Treponema pallidum*, and HSV-2. 100% agreement was demonstrated between the two assays.	The sponsor tested 32 HSV negative samples which were positive for Cytomegalovirus, Epstein Barr virus, Virus Capsid antigen, Human herpesvirus6 or Varicella zoster virus. Eight of the samples were found to be positive with the Focus Immunoblot, while the 24 remaining samples were negative.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
Labeled Performance Characteristics		
Limitations	A negative test result does not completely rule out the possibility of an infection with HSV-1 as individuals may not exhibit any detectable IgG antibodies at the early stage of acute infection. False negative results may occur when the HSV virus is glycoprotein G (gG) deficient (0.2 % HSV isolates were gG deficient). The detection of HSV-1-specific IgG antibodies in a single sample indicates a previous exposure to HSV-1 but does not give any information of the time point of an exposure. Results from the Elecsys HSV-1 IgG immunoassay should be used in conjunction with the patient's medical history and clinical symptoms. The results in HIV patients, in patients undergoing immunosuppressive therapy, or in patients with other disorders leading to immune suppression, should be interpreted with caution. Specimens from neonates, cord blood, pretransplant patients or body fluids other than serum and plasma, such as urine, saliva or amniotic fluid have not been tested.	The performance of this assay has not been established for the general population. The performance of this assay has not been established for ruling out diseases with similar symptoms, e.g., *Candida albicans, Bacteriodes species, G. vaginalis, Mobiluncus* species. Instead, also use culture or other appropriate methods. The performance of this assay has not been established for matrices other than serum, or visual result determination(s), or monitoring HSV therapy. All results from this and other serologies must be correlated with clinical history, epidemiological data, and other data available to the attending physician in evaluating the patient. The prevalence of infection will affect the assay's predictive value. As with other serological tests, negative results do not rule out the diagnosis of herpes smiplex disease. The time required to seroconverst following the primary infection varies with the individual; the specimen may have been drawn prior to the appearance of detectable antibodies.

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510(k) Summary, Continued

Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
Labeled Performance Characteristics		
Limitations, continued	The assay is unaffected by icterus (bilirubin < 1130 µmol/L or < 66 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1000 mg/dL), lipemia (Intralipid < 2000 mg/dL), biotin (< 287 nmol/L or < 70 ng/mL), and rheumatoid factor (< 1500 IU/mL). Criterion: Mean recovery of positive samples within ± 20 % of serum value. Correct assignment of negative samples and recovery of positive samples ± 20 %. Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration. No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL. In vitro tests were performed on 18 commonly used pharmaceuticals and in addition on Famciclovir, Aciclovir and Valaciclovir. No interference with the assay was found. Assay performance for sodium citrate plasma has not been evaluated.	False negative results may occur when the infecting virus is gG deficient, or because it is unknown if the assay's antigen was glycosylated the same as mammalian cells. As with other serological tests, false positive results may occur. Repeat testing or testing with a different device may be indicated in some settings, e.g., patients with a low likelihood of HSV infection. A single positive result only indicates previous immunologic exposure; level of antibody response or class of antibody response may not be used to determine active infection or disease state. The magnitude of the index value above the Cut-off does not indicate the total amount of antibody present. Serology cannot distinguish genital from oral infections. When appropriate, culture is recommended to identify the infection site. However, false negative HSV cultures are common, especially in patients with recurrent infection or with healing lesions.

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
Labeled Performance Characteristics		
Limitations, continued	In rare cases, interference due to extremely high titers of antibodies to streptavidin or ruthenium can occur. These effects are minimized by suitable test design. Cross reactivity for HPV and various types of bacterial vaginosis-causing agents (e.g., *Mobiluncus* spec, *Gardnerella vaginalis*, and *Bacteroides* spec) were not evaluated in the performance analysis of this assay. The influence of the serological response against any of these agents on the results of the Elecsys HSV-1 IgG immunoassay is unknown. Sample stability studies were performed using serum only. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	

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Comparison of Assays—Similarities and Differences, continued

Immunoassay Comparison		
Feature	**Elecsys HSV-1 IgG Immunoassay (Candidate Device)**	**Focus HerpeSelect 1&2 (Predicate Device: K000238)**
Labeled Performance Characteristics		
Percent Agreement or Sensitivity/ Specificity	***Expectant Mother Cohort (n=125)*** Positive Percent Agreement (95% CI): 91.0% (82.4-96.3%) Negative Percent Agreement (95% CI): 95.7% (85.5-99.5%) ***Sexually Active Cohort (n=600)*** Positive Percent Agreement (95% CI): 94.2% (91.3-96.4%) Negative Percent Agreement (95% CI): 90.3% (85.9-93.8%) ***Low Prevalence Cohort (n=200)*** Positive Percent Agreement (95% CI): 94.9% (87.4-98.6%) Negative Percent Agreement (95% CI): 96.7% (91.8-99.1%)	**Relative Sensitivities to Western Blot** Pregnant Cohort: 100% Sexually Active Adults: 99.3% Low Prevalence Population: 82.4% **Relative Specificity to Western Blot** Pregnant Cohort: 93.1% Sexually Active Adults: 95.1% Low Prevalence Population: 100%
Agreement with CDC Panel	100%	100%

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Comparison of Controls – Similarities and Differences

Characteristic	PreciControl HSV (Candidate Device)	Predicate Device: Elecsys PreciControl Anti-CCP (K081338)
Intended Use	PreciControl HSV is used for quality control of the Elecsys HSV-1 IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.	Elecsys PreciControl Anti-CCP is used for quality control of the Elecsys Anti-CCP immunoassay on the Elecsys and **cobas e** immunoassay analyzers.
Levels	Two	Two
Format	Lyophilized	Lyophilized
Matrix	Human serum negative for HSV-1 IgG antibodies	Human serum
Analyte Concentration	PreciControl 1: ~ 0.30 COI PreciControl 2: ~ 4.00 COI	PreciControl 1: ~20 U/mL PreciControl 2: ~100 U/mL
Stability	Unopened: • Store at 2-8°C up to the stated expiration date Reconstituted: • 2 - 8°C: 14 days • On the Elecsys 2010 and **cobas e** 411 analyzers at 20-25°C: Up to 5 hours • On the MODULAR ANALYTICS E170, **cobas e** 601, and **cobas e** 602 analyzers: Up to 2 hours	Unopened: • Store at 2-8°C up to the stated expiration date Reconstituted: • -20°C: 1 month (freeze only once) • On the analyzers at 20-25°C: Up to 5 hours • After thawing: Use only once
Handling	Dissolve carefully the contents of one bottle by adding exactly 3.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Use a pipette to transfer the reconstituted control of 1 bottle into empty labeled Elecsys snap-cap bottles supplied.	Dissolve carefully the contents of one bottle by adding exactly 2.0 mL of distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam. Transfer aliquots of the freshly reconstituted controls into appropriate tubes for storage. Store the aliquots immediately at -20°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 25 2012

Roche Diagnostics
c/o Ms. K. Colleen Adams, MTSC
Regulatory Affairs Principal
9115 Hague Road, P.O. Box 50416
Indianapolis, IN 46250-0146

Re: K120625
Trade/Device Name: Elecsys HSV-1 IgG Immunoassay and PreciControl HSV
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes simplex virus serological assays
Regulatory Class: Class II
Product Code: MXJ, JJX
Dated: June 25, 2012
Received: June 26, 2012

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: **Elecsys HSV-1 IgG Immunoassay**

Indications For Use: The Roche Elecsys HSV-1 IgG immunoassay is a test for the *in vitro* qualitative determination of IgG class antibodies to HSV-1 in human serum and lithium-heparin plasma, K2 EDTA plasma, and K3 EDTA plasma. The test is intended for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-1 infection. The predictive value of positive and negative results depends on the population's prevalence and the pretest likelihood of HSV-1.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.

This test is not FDA-cleared for screening blood or plasma donors.

The performance of this assay has not been established for use in a pediatric population, neonates, immunocompromised patients, or for use at point-of-care facilities.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K120625

Indications for Use

Device Name: **PreciControl HSV**

Indications For Use: PreciControl HSV is used for quality control of the Elecsys HSV-1 IgG immunoassay on the Elecsys and **cobas e** immunoassay analyzers.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k 120625